Remarks

This is in response to the February 2, 2010 Office Action issued in the above-identified patent application. A Request for a one-month Extension of Time (and fee), and a Terminal Disclaimer accompany this Reply.

I. Status of Claims

Claims 1-44, as originally filed, were subject to a Restriction Requirement, and applicants elected, without traverse, the Group I claims 1-26 and 44, drawn to an immediate release pharmaceutical tablet with at least two segments … (a), … (b), … or (c). In addition, applicants elected the single species (a), reciting two or more segments with same drug or drugs. Applicants submitted that claims 1-10, 12-26 and 44 were readable on the elected species. According to the Office Action, claims 6, 11-14, 24, and 27-43 are withdrawn from consideration since claims 1-5, 7-10, 12, 15-23, 25-26, and 44 read on the elected species and are being examined for purposes of the instant Office Action.

Of these examined claims, claims 1 and 2 have been amended, and claims 3, 7, 23, and 25-26 have been canceled to remove language directed to a non-elected species. In addition, certain claims have been amended to change the dependency from canceled or withdrawn claims to now depend from a pending claim. Accordingly, claims 1-2, 4-5, 8-10, 15-22, and 44 are pending. No new matter is presented by the amendments to the claims. Reconsideration of these pending claims, as amended, is respectfully requested.

II. Claim Rejections – Obviousness-Type Double Patenting

Claims 1-5, 7-10, 12, 15-23, 25-26, and 44 are rejected on the ground of non-statutory obviousness-type double patenting over US Patent No. 7,329,418. Applicants submit herewith a Terminal Disclaimer, which is believed to obviate this double patenting rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-5, 7-10, 12, 15-23, 25-26, and 44 are also rejected on the ground of non-statutory obviousness-type double patenting over co-pending US Patent Application, Ser. No. 10/598,367. Applicants will consider filing a Terminal Disclaimer in order to overcome this double patenting rejection when claims are deemed allowable in the instant application or the cited co-pending application.

III. Claim Rejections – Anticipation under 35 USC 102

Claim 1 is rejected under 35 USC 102(b) as being anticipated by US Patent No. 4,258,027 (the '027 patent). The Office Action cites the '027 patent as teaching a multi-fractionable tablet structure configured as a unitary dosage while having readily severable sub-dosage units and score markings readily permitting accurate equal bisectional or trisectional fracture as desired for patient consumption, and containing one or more active ingredient. Applicants respectfully traverse.

The '027 patent cannot anticipate the invention as recited in claim 1 because the '027 patent does not teach or in any way describe each and every element of the claimed invention, as required for anticipation. According to claim 1, the tablet has at least two segments. The term "segment" is expressly defined within the specification as relating to layers. The '027 patent describes only single-layer, homogeneous compositions having scores. The '027 patent does not describe tablets having two or more layers (segments). Because the '027 patent fails to describe each and every element of the claimed invention, it cannot properly serve as an anticipating reference. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 1 is also rejected under 35 USC 102(b) as being anticipated by US Patent No. 3,336,200 (the '200 patent). Again, however, the '200 patent fails to describe tablets having two or more segments (layers). Because the '200 patent fails to describe each and every element of the claimed invention, it cannot properly serve as an anticipating reference. Reconsideration and withdrawal of this rejection is also respectfully requested.

Claims 1-5, 7-10, 12, 15-23, 25-26, and 44 stand rejected under 35 USC 102(b) as being anticipated by US Patent No. 6,183,778 (the '778 patent). A fair reading of the '778 patent reveals that the described tablets provide different release rates for two different drugs within the tablets. Therefore, the tablets of the '778 patent are "controlled-release" tablets and are not immediate-release tablets as claimed. This distinction removes the '778 patent from anticipating the subject invention; applicants respectfully request reconsideration and withdrawal of this rejection as well.

IV. Claim Rejections – Obviousness under 35 USC 103

Claims 1-5, 7-10, 12, 15-23, 25-26, and 44 stand rejected under 35 USC 103(a) as being unpatentable over the '027 patent, the '200 patent, and the '778 patent.

As stated above, the '027 and '200 patents fail to describe layered (segmented) tablets in accordance with the claimed invention. The '778 patent, though describing layered tablets, is limited to controlled-release tablets and fails to describe immediate-release tablets as claimed. Applicants respectfully submit that, even in combination, the cited references fail to describe the claimed invention because there is no teaching or suggestion in the prior art to provide immediate-release active compositions, configured as a layered or segmented tablet as claimed.

The layered or segmented configuration for the claimed tablets provides the unexpected advantage of being able to accurately and precisely divide the doses (contained in the discrete active segments) by splitting the tablet through the inactive segment only, and thereby separating the doses in the active segment without significant negative effect to the integrity of those active segments. Clearly, the '027 and '200 patents are limited to single-layer, homogenous tablets that are divided through the active portion of the tablet, and are not divided through the inactive portion as provided by the claimed tablets.

Moreover, the '778 patent relates solely to controlled-release tablets. It is well known and accepted in the pharmaceutical arts that breaking a controlled-release layer or composition can negatively affect the controlled-release properties of that composition because the surface area is modified and may allow solvent (e.g., body fluids) to change the

dissolution profile of the controlled-release portion of the tablet, thus destroying the intended operability of the controlled release tablet. Controlled-release tablets of the '778 patent are not intended to be divided; they are only intended to be taken whole, so that the two different drug compositions within the tablet are released at different rates following administration of the whole tablet.

Applicants respectfully submit that there is no motivation provided within the prior art to combine a layered, controlled-release tablet (as in the '778 patent) with non-layered or non-segmented tablets having scoring patterns to allow for breaking the tablet and dividing the dose (as in the '027 and '200 patents). Nor is there any motivation provided within the prior art to modify the non-layered or non-segmented tablets of the '027 or '200 patents to provide layered tablets as in the '778 patent because the layered tablets of the '778 patent are controlled-release tablets that are not intended to be broken or divided.

In view of the above distinctions, and the failure of the prior art to provide a teaching or suggestion of the subject invention, as well as failing to provide any motivation to combine the teachings in the cited references or any teaching, suggestion, or motivation to modify the tablets described in the cited references, applicants believe the claimed tablets are clearly not obvious in view of these cited references. Reconsideration and withdrawal of the rejections under 35 USC 103(b) is respectfully urged.

Applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request issuance of a Notice of Allowance. Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

Respectfully submitted,

Dated: May 11, 2010

/Ted W. Whitlock/

Ted W. Whitlock
Registration No. 36,965
5323 SW 38th Avenue
Ft. Lauderdale, Florida 33312
Ph: 954-986-2119
Fax: 954-986-2120